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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,356	09/20/2003	Craig A. Rosen	PS904	4830

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,356	ROSEN ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13,16,17,20,21 and 24-33* is/are pending in the application.

4a) Of the above claim(s) *20,21,24 and 31-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,16,17 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/31/05;3/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. Applicant's election without traverse of Group II (claims 11-13 and 17 SEQ ID NO:1562) on March 16, 2006 is acknowledged. Applicant's comments regarding a rejoinder of method claims upon notification of an allowable product is noted.

Claim Disposition

2. Claims 1-10, 14-15, 18-19 and 22-23 are cancelled. Claims 25-33 have been added. Claims 11-13, 16-17, 20-21, 24-33 are pending. Claim 16 has been rejoined based on the amendments made to the claim. Claims 11-13, 16-17 and 25-30 are under examination. Claims 20-21, 24 and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

3. The Amendment filed on March 16, 2006 has been received and entered.

Specification

4. The specification is objected to because of the following informalities:

(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TAQMAN®, AMPLITAQ GOLD®, for

example, have been noted in this application (see page 33). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. As the specification is large, applicant is urged to review it for other occurrences.

(b) The specification is also objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See for example pages 35, 38 and 3438. It is suggested that http:// is deleted. As the specification is large, applicant is urged to review it for other occurrences.

(c) On page 3410, the following typographical error appears, "Production of IL-8 by by endothelial cells...".

Correction is required.

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in

the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

The examiner reviewed U.S. Application No. 10/100,683, U.S. Patent Nos. 6,878,687 and 6,590,075 and did not find support for the structure of the polypeptide. For example, The cDNA clone HWHGU54 which encodes SEQ ID NO:1562 was not found. It is noted that Application No. 10/100,683 has SEQ ID NO:1562, however, it is a DNA sequence. Therefore, this application will not get the Priority date of the application or patents listed above only the filing date of the present application which is September 20, 2003.

Claim Objection

6. Claims 17 and 30 are objected to because of the following informalities:

Claim 17 is objected to because the claim does not further limit claim 16 which has the polypeptide. See also claim 30.

Correction of the above is required.

Information Disclosure Statement

7. The Information Disclosure Statement (IDS) filed on August 31, 2005 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action. Note that the IDS filed on March 16, 2006 is a duplicate of the August 31, 2005, thus has been lined through.

Compliance with the Sequence Rules

8. The A signed statement regarding the sameness of the CRF and the paper copy of the sequence listing was received September 20, 2003; however the statement does not affirm that no new matter is included in the CRF. Therefore, the instant application fails to fully comply with the sequence rules. A signed statement regarding no new matter is required.

Claim Rejections - 35 USC 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

9. Claims 11-13 and 25-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 11 and the dependent claims hereto are drawn to a polypeptide, which reads on a product of nature. The claims should be amended to indicate the hand of the inventor, for example the insertion of isolated or purified in connection with the polypeptide to identify a product not found in nature (see MPEP 2105).

Claim Rejections-Utility Rejections Under 35 USC § 101 And 35 USC 112, First Paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 11-13, 16-17 and 25-30 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility. Claims 11-13, 16-17 and 25-30 are directed to a polypeptide, which are not supported by either a specific and substantial asserted utility or a well-established utility. The specification fails to provide objective evidence of any activity for the proteins. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent or implied by the specification's disclosure of the properties of a material. There is no specific disease or specific function that is suggested for the polypeptides. It is noted that page 23 of the specification indicates that the invention relates to human secreted proteins/polypeptides, and isolated nucleic acid molecules encoding said proteins/polypeptides, useful for detecting, preventing, diagnosing, prognosticating, treating and/or ameliorating cancer and other hyperproliferative disorders, however, no specific association is made or demonstrated. No real association is made between a specific disorder/disease and the claimed product. A

search of the claimed sequences produced a reference that teaches a protein that is 100% identical to the claimed sequence (SEQ ID NO:1562) is used for treating pathologies relating to reproductive abnormalities, involving spermatogenesis and endocrinological defects (see U.S. Patent No.6,600,019 and the alignment) which does not substantiate the claimed invention.

The specification does not disclose any particular conditions wherein there is a deficiency or overproduction of the claimed polypeptide. What disorder/disease results from a decreased expression or activity of the polypeptide, the specification does not disclose specific information. No evidence is provided, for example, that the encoded polypeptide is not expressed in healthy tissues. It could be a constitutively expressed gene, and thus would not be useful in developing drugs for any disease. Even if it were differentially expressed in disease tissues, for example, there is no indication regarding how to develop a drug to treat specific diseases, because there is no information disclosed regarding the role the polypeptide plays in healthy tissue. For example, page 23 of the instant specification state that the proteins are useful for detecting, preventing, diagnosing, prognosticating, treating and/or ameliorating cancer and other hyperporliferative disorders, however, no evidence is provided of the reduction in cancer or the treatment of cancer nor is there any evidence of said protein in association with any and all types of cancer disease. Thus, no empirical evidence exists on the record to demonstrate the association as claimed between the claimed protein and cancer or any other diseases/disorders. The specification contains several Tables, which do not provide any evidence to demonstrate nor describe the claimed invention. Therefore, the

reference does not substantiate the instant disclosure that the protein can treat cancers or any other disease or provide support for a substantial utility.

The specification asserts that the product of the invention can be used (1) as drugs for the treatment or prevention of cancer (2) in diagnosing disease and (3) as probes. As for drugs for the treatment or prevention of cancer, this asserted utility is not substantial. The specification does not disclose any particular conditions wherein there is a deficiency, overproduction, or altered form of the claimed polypeptides. The fact that the polynucleotide can be found in libraries of cells isolated from for example, cancerous tissues or immune system cells would not indicate to one of skill in the art that the protein is involved with any of the above conditions. Even if it were differentially expressed in disease tissues, for example, there is no indication regarding how to develop a drug to treat any specific disease based on the protein, because there is no information disclosed regarding the role the protein plays in healthy tissue. Significant further experimentation would be required of the skilled artisan to identify individuals who would benefit from such a drug, and then to determine a best course of treatment. There is no disclosure, for example, of how to assay for improvement or intolerable levels of side effects or dosages of the drug. Since this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

It is asserted that the invention can be used in diagnosing disease with the protein, this assertion is not substantial. The specification does not disclose any specific diseases associated with altered levels or forms of the protein as discussed

above. Significant further experimentation would be required of one skilled in the art to identify individuals having such a disease. There is no indicia, for example, of any symptoms associated with such a disease/disorder. As this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. The assertion is made of a use as probes; however, this utility is not specific, as this can be done with any polynucleotide. Expressed polynucleotides have a variety of general uses, for example, as a probe for hybridization or as a template for protein expression, these uses are applicable to any expressed polynucleotide and are not specific to the encoding polynucleotide. MPEP 2107.01 states that, "Utilities that require or constitute carrying out further research to identify or reasonably confirm 'real world' context of use are not substantial utilities".

In view of the foregoing, and absent data/evidence, the claimed invention lack utility. See *Brenner v. Manson*, 383, U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment. See also the Utility Guidelines available at www.uspto.gov.

11. Claims 11-13, 16-17 and 25-30 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth

above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Undue experimentation is required to practice the claimed invention as the specification lacks adequate deposit information as discussed below. In addition the amount of experimentation required to practice the claimed invention is undue as the claims encompass an unspecified amount of fragments that are not supported by the instant specification. The polypeptide as claimed once modified might not have the same properties of the native/wild-type protein or retain the same function or could have no biological activity. In addition, claims reciting percent sequence identity, for example 95% sequence identity do not indicate where variations will occur or what variations can be tolerated in the sequence. Further, the claimed invention is directed to fragments of at least 30 or 50 amino acid residues and there is no indicia as to which 30 or 50 residues or if the residues are contiguous. The instant specification does not demonstrate or provide guidance as to what the structure of the protein will be once modified or if said protein will be functional or exhibit the same properties or characteristics as the native protein. In the instant application, the partial structure in the form of the recited percent identity is insufficient to determine a chemical structure for the variants encompassed in the claims. Note also that the claims do not recite a specific activity.. The claims do not require, any conserved regions or that the fragments have a contiguous stretch of amino acids.

Additionally, there is no data provided demonstrative of a particular portion of the structure that must be conserved. Note that the claims do not have a functional

limitation, thus, modifications to the polypeptide sequence, may result in a protein that is at best has a different function or at worst has no activity. It is noted that claim 1 item (c-d) recites "has biological activity", however, no specific activity is given. Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation.

Predictability of which potential changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (for example, expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, for example, multiple substitutions. In this case, the necessary guidance has not been provided in the specification. Therefore, while it is known in the art that many amino acid substitutions are possible in any given protein, the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited, as certain positions in the sequence are critical to the protein's structure/function relationship. It is also known in the art that a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule

in many cases. For example, various sites or regions directly involved in binding activity and in providing the correct three-dimensional spatial orientation of binding and active sites can be affected (see Wells, Biochemistry, vol. 29, pages 8509-8517, 1990). The instant specification provides no guidance/direction as to which regions of the protein would be tolerant of modifications and which would not, and it provides no working examples of any variant sequence that is encompassed by the claims. It is in no way predictable that randomly selected mutations, such as deletions, substitutions, additions, etc., in the disclosed sequences would result in a protein having activity comparable to the one disclosed. As plural substitutions for example are introduced, their interactions with each other and their effects on the structure and function of the protein is unpredictable. The skilled artisan would recognize the high degree of unpredictability that all the fragments/variants encompassed in the claims would retain function. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).*

The state of the prior art provides evidence for the high degree of unpredictability as stated above. Seffernick et al. (J. Bacteriology, vol. 183, pages 2405-2410, 2001) disclose two polypeptides having 98% sequence identity and 99% sequence identity,

differing at only 9 out of 475 amino acids (page 2407, right column, middle and page 2408, Fig. 3). The polypeptides of Seffernick et al. are identical along relatively long stretches of their respective sequences (page 2408, Fig. 3), however, these polypeptides exhibit distinct functions. The modifications exemplified in the Seffernick et al. reference is small compared to those contemplated and encompassed by the claimed invention. In addition, Guo et al. (PNAS, vol. 101, no.25, pages 9205-9210, 2004) disclose that a third of single amino acid changes would completely inactivate the average protein and the more substitutions made the more probability that the protein will be inactivated. Thus, this gives the sense of what one of skill in the art can expect when a claim embraces fragments with up to 10, 20, 30, 40 or more amino acid changes and how many mutants one of skill in the art can test in such an endeavor. Note that the claims broadly recite at least 30 or at least 50amino acids, or sequential deletions, thus no limit on the size of the fragment or how much variability will occur in the protein claimed.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims. Furthermore, while recombinant and mutagenesis techniques are known in the art, it is not routine in the art to screen large numbers of mutated proteins where the expectation of obtaining similar activity is unpredictable based on the instant disclosure. The amino acid sequence of a protein determines its structural and functional properties, and predictability of what mutations can be tolerated in a protein's sequence and result in certain activity, which is very complex, and well outside the realm of routine

experimentation, because accurate predictions of a protein's function from mere sequence data are limited, therefore, the general knowledge and skill in the art is not sufficient, thus the specification needs to provide an enabling disclosure.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed fragment. The nature and properties of this claim is difficult to ascertain from the examples provided, as one of skill in the art would have to engage in undue experimentation to construct the variants of the claimed invention and examine the same for function.

The specification does not provide support for the broad scope of the claims, which encompass an unspecified amount of fragments. The claims broadly read on any fragment thereof for the given sequence (SEQ ID NO: 1562). The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)*. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use

the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to construct and test fragments of the claimed invention would constitute undue experimentation. Making and testing the infinite number of possible fragments to find one that function is undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

12. Claims 11-13, 16-17 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a polypeptide that comprises a first amino acid sequence at least 95% identical to a second amino acid sequence selected from for example a full length polypeptide of SEQ ID NO: 1562 or polypeptide fragment of at least 30 amino acids etc. (see claim 1). No function is associated with the protein. The claims are directed to fragments of the claimed protein and the claims are absent functional language, therefore, a skilled artisan would not know if said fragments had the same function as the wild-type or a different function. The specification lacks

adequate written description to demonstrate to a skilled artisan that applicant was in possession of the claimed invention.

In addition, the claimed invention lacks complete deposit information. The specification on page 26 makes reference to deposits made to ATCC, and the claims are directed to ATCC Deposit No. 209782, however, this is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met, because the specification does not indicate whether the sequence of the invention contained in ATCC Deposit No. 209782 is known and publicly available or can be reproducibly isolated. Without publicly available deposit information one skilled in the art could not be assured of the ability to practice the invention as claimed. It is noted that applicant made the deposits under the Budapest Treaty, however, the specification need to be amended to disclose the date of the deposit and the public availability of the deposit (Table 1A is acknowledged, however, insufficient). For further information concerning deposit practice, applicants attention is directed to *In re Lundark* 773 F 2d 1216 227 USPQ CCAFC and 37 CFR 1.801-1.809.

Moreover, the claims are directed to protein sequences that comprise sequential deletions from the C or N terminus and there is no limit on the amount of amino acids that can be deleted, and no demonstration of any conserved region or the effects of the modifications contemplated.

Thus, in view of the foregoing the claimed invention lacks proper written description and the skilled artisan cannot envision the detailed chemical structure of all the claimed fragments encompassed by the claims. Additionally, the instant

specification has not provided a representative number of species for the claimed genus. A representative number of species means that the species, which are adequately described are representative of the entire genus. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. The claimed genus of polypeptides could include non-functional proteins or proteins with a different function than the one described. Therefore, the genus of claimed polypeptides encompasses widely variant species. Based on the unlimited variations contemplated one skilled in the art would at best expect a protein that is different or at worst a protein that is not functional.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of

ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. *See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993).*

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 11-13, 16-17 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 1 is indefinite for the recitation of "wherein said fragment has biological activity", because it is unclear what activity is being referred to, thus the metes and bounds of the claim is not clearly defined. A skilled artisan would not know when they

were in possession of the claimed invention, with an undefined fragment. The dependent claims hereto are also included.

Claim 12 is confusing, as the claim recites "the polypeptide of claim 11, wherein said polypeptide comprises a heterologous amino acid sequence and it is unclear whether this sequence is the first or second amino acid sequence, or both recited in claim 11.

Claim 13 is indefinite for the recitation of "comprises sequential amino acid deletions" as the entire C or N terminus could be deleted as there is no upper limit.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 11, 16-17, 25, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Prayaga et al. (U.S. Patent No. 6,600,019, January 6, 2000).

Prayaga et al. teach a sequence that is identical to the claimed SEQ ID NO:1562. Although the patented sequence is 414 residues it also reads on the "at least 30 amino acids" and "at least 50 amino acids" as "at least" is open and can be any number up to

414. In addition, claims 16 and 29 are anticipated as the patent discloses production of the protein by a cell and the same protein structure. Therefore, the limitations of the invention are met by the reference.

Conclusion

15. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

4/21/06

HOPE ROBINSON
PATENT EXAMINER